UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

25181 7590 11/26/2007

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/166,701	ODIDI ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 7-12, 23, 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-12, 23 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **8/27/07** presents remarks and arguments to the office action mailed **4/26/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1, 4, 7-12, 23, 28-33 are pending in this office action. Claims 1, 9, 3032-33 have been amended and claims 2-3, 5-613-22 and 24-27 have been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 7-8, 9-12, 23, 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite percentages of different agents such as 1-50% by weight polymers of acrylic acid crosslinked with

polyalkenyl alcohols, 1-15% by weight of mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose etc., but fail to state to what these percentages are based upon. It is not clear whether the percentages of the itemized agents in the claims are part of the matrix.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss et al, US 4,252,786.

The reference teaches a controlled release tablet comprising polymers of acrylic acid crosslinked with polyalkenyl alcohols. See col. 2, lines 40-46. Note that sucrose is a sugar alcohol. Also see tablets composition, wherein the composition comprises hydroxymethyl cellulose, ethyl cellulose and hydroxypropyl methyl cellulose talc. Note that magnesium stearate is about 0 %. See col.5, lines 26-44 and col. 6, lines 8-24. It is anticipated that these agents will perform the there necessary functions as combine because the term "about" permits some tolerance.

The reference also teaches the corsslinked polymers of acrylic acid and polyalkenyl alcohols are carboxyvinyl polymer resins. See col. 2, line 40.

Also the reference teaches the active agent as required by instant claims 9 and 10 the addition of an active agent as medicaments. The active agent is anticipated to

comprise more than 1% of medicament. See col. 2, lines 64-68. With regard to claim 8, the granulating and tableting aids are taught at col. 3, lines 25-55. It is interpreted by the Examiner that it inclusion in the composition is functional. Less than 0, is interpreted that it can be omitted. Ethyl cellulose is taught as required by instant claim 9 also see table 3, col. 6, lines 8-24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 7-12, 23 and 28-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al, US 4,252,786 in view of Guley et al., US 4,309,405 (of record) taken with Kooichi et al. US 4,218,433.

Weiss et al. is applied here as in the above rejection. Claims 23, 30 and 32-33 are taught in part as already discussed in the above rejection. With regard to claims 11 and 29 the reference teaches the active agent to be aspirin a non-steriodal anti-inflammatory drug (NSAID). See col. 5, line 3. One of ordinary skill in the art would have been motivated to switch aspirin to naproxen another drug of the same category (NSAID) and expect success in doing so.

Guley et al teach a controlled release (tablet) core comprising 20% drug and a mixture of water soluble and water-insoluble polymers at a ratio of 10:1-1.5:1 (column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 2 lines 42 and 48-49). Sustained release is specified (Title).

Talc and calcium stearate are specified (example 1 column 51). One of ordinary skill in the art would have been motivated to substitute calcium for magnesium and expect a successful result in doing so because both calcium and magnesium are alkaline earth metals and the would have expected the same result because of the shared properties. Guley et al. further teach plural water-soluble polymers including hydroxypropyl methyl cellulose and hydroxy propyl cellulose (column 2 lines 40-44).

The combine references do not teach the addition of methacrylic to the said composition, however, Kooichi et al. teach a controlled release tablet formation comprising methacrylic and methacrylic esters. See col. 2, lines 18-30.

One of ordinary skill in the art would have been motivated to combine the above cited references and form a controlled release tablet with a medicament is released

either at a sustained or pulsative delivery period of time. The above references make it obvious to one of ordinary skill in the art to make and use the claim invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn. Since this is not the only rejection remaining, the double patenting rejection is therefore maintained below.

Claims 1,4,7-12, 23 and 28-33 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 - 22** of U.S. Patent Application No. **11/473,386**. Although the conflicting claims

are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to a pharmaceutical compositions in the current application (claims 1,4,7-12, 23 and 28-33) and (claims 14-17) in the copending application. The copending application anticipates the claims of the instant application.

The claims of the co-pending application recite a polysaccharide and an uncrosslinked linear polymer and that of the instant claims recite using polymers of acrylic acid cross linked with polyalkenyl alcohols and hydroxyethyl cellulose which are obvious variation of the co-pending application claims. See current application claims 1,4,7-12, 23 and 28-33 and copending application claims 14-17. The compositions recited in the claims are anticipatory of each other.

As to the copending application claims 1-13 and 18-22, these claims refer to a device and a method of treating. The device and method of treating would have been used for the delivery of the pharmaceutical composition of claims 14-17 in the copending application. Thus, the process of making a composition and using a device are a set of precursor steps to the process of treating and therefore are part of the obvious variation of the copending application claims compared to the current application claims.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

Claims 1,4,7-12, 23 and 28-33 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 - 28** of U.S. Patent No. **7090867**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The claims of the patent refer to a method of making a controlled release whilst the claims of the instant application refer to a pharmaceutical composition of a controlled release delivery device. The current application (claims 1,4,7-12, 23 and 28-33) and a method of making a controlled release pharmaceutical composition (claims 1-28) in the patented claims. The current application claims anticipate the patented claims

As to the patented claims 1-28, these claims refer to a method of making the controlled release drug using a microbial polysaccharide and cellulose which are obvious variation of the instant claims compositions. The method of making would have resulted in the formation of a controlled release pharmaceutical composition in the patented claims. Thus, the process of making a composition are a set of precursor steps leading to a controlled release formulation and therefore are part of the obvious variation of the patented claims compared to the current application claims.

In view of the foregoing, the patented claims and the current application claims are obvious variations.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
11/09/07

11/13/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER